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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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HOFFMANN-LA ROCHE INC. PATENT LAW DEPARTMENT 340 KINGSLAND STREET NUTLEY, NJ 07110				
EXAMINER MENON, KRISHNAN S				
ART UNIT 1723		PAPER NUMBER		
DATE MAILED: 10/29/2003				

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/075,733

Applicant(s)

BEHRENDT ET AL.

Examiner

Krishnan S Menon

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 September 2003.
- 2a) ☒ This action is FINAL. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-26,42-44 and 47 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-26,42-44 and 47 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: |

DETAILED ACTION

Claims 1-26, 42-44 and 47 are pending.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-4, 6, 10-12, 19, 21, 25 and 43 are rejected under 35 U.S.C. 102(e) as being clearly anticipated by Zha et al (US 6,524,481 B2).

Zha (481) teaches a hollow fiber membrane module (figures) comprising a housing (9-fig 1), plurality of hollow fibers (6) arranged parallel, wherein the volumetric ratio of the membranes to packing space is less than 10% (col 4 lines 27-29, claims 13, 14) as in instant claim(s) 1. Housing is cylindrical as in instant claim(s) 2 (fig 3B, 4B). Lateral housing surface has openings as in instant claim(s) 3 (9-fig 1-4) having shapes squares, etc as in instant claim(s) 4 (51-fig 9). Ratio of opening area to housing surface area is about 0.2 to 0.9 as in instant claim(s) 6 (see figures). The fibers are arranged in the form of a bundle as in instant claim(s) 10 (figures). At least two fiber bundles are separated by a segmentation element fitted on the lateral surface of the housing as in instant claim(s) 12 (see fig 9, 10). The length of at least one segmentation element corresponds to the length of the

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housing as in instant claim(s) 19 (figures, col 8 lines 20-27). Segmentation elements are as long as the pottings provided at the ends, and the pottings are segmented as in instant claim(s) 21 (Fig 9). Module comprises connections for feeding liquid into and withdrawing from the hollow fiber as in instant claim(s) 25 (fig 7,8). Claim 11 is a product by process claim having structural elements as in claim 10, and therefore, is not patentable. [{"[E]ven though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." In re Thorpe, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985)]. Regarding claim 43, the low range of packing density, below 20% (col 4 lines 27-29), with the 2 mm fiber diameter would make the fiber count less than 10 per centimeter (The examiner believes this should be square centimeter, and is assumed as such for examination).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

1. Claim 5 is rejected under 35 U.S.C. 103(a) as being unpatentable over Zha (481).

Zha (481) teaches all the elements of claim 5 as in claim 3 above, except the size of the openings on the lateral surface of the housing. However, it would be obvious to one of ordinary skill in the art at the time of invention to provide openings of about 3 to 20 mm on the screen type housing of Zha (see fig 9) to prevent excessive movement of the fibers and to have clear flow passage.

2. Claims 13 – 16, 20 and 22-24 rejected under 35 U.S.C. 103(a) as being unpatentable over Zha (481) in view of Young et al (US 5,282,964).

Zha (481) teaches the elements of the instant claims as in claim 10 above, except: segmentation elements having a frame surrounding a free passage surface as in claim 13, the frame subdivided into stabilization elements as in 14, ratio of openings to total surface area of the stabilization elements being 2-20% as in claim 15, segmentations elements fitted to the inner surface of the housing to subdivide into compartments as in claim 16, segmentation elements shorter than the housing as in claim 20, hollow fibers arranged in compartments produced by segmentation elements as in claim 22 and fixed on the segmentation elements as in claim 23.

Young teaches a housing with segmentation elements attached on the inner surface of the housing, segmentation elements shorter than or equal in length to the housing, dividing the housing into compartments and having hollow fiber bundles contained in the compartments (see fig 3, parts 32, 30). Young teaches the segmentation elements and the housing to be impervious. However, it

would be obvious to one of ordinary skill in the art at the time of invention to have the housing and segmentation compartment construction of Young in the module of Zha (481) with the material of the housing and the segmentation elements as the lattice type screen of Zha (481) for supporting the hollow fibers and preventing excessive movements of the hollow fibers while providing free passage for the fluids and air bubbles as taught by Zha (see figure 9 and col 8 lines 12-27).

Regarding the additional elements of claim 24, the packing density of the fibers is less than 20% as taught by Zha (col 4 lines 27-29).

3. Claims 7-9, 26 and 42 are rejected under 35 U.S.C. 103(a) as being unpatentable over Zha (481) in view of EP 1 008 358 A2

Zha (481) teaches all the elements of the instant claims as in claim 1 above except the material of the hollow fiber as in claim 7, and material capable of sterilizing at 121°C as in claim 26. EP (358) teaches polymeric (polysulfones, cellulosic, etc) hollow fiber membranes (see specification of EP). It would be obvious to one of ordinary skill in the art at the time of invention to use the polymeric hollow fiber as taught by EP (358) in the teachings of Zha (481) for the module for having hydrophilic material for application like water treatment. Regarding the material being resistant to steam at 121°C, the material taught by EP(358) is the same as what the instant application recites, and therefore, should withstand the same temperature.

Claims 8, 9 and 42 have additional elements which are taught by Zha (481) as follows:
Thickness of membrane from 5 to 300 microns as in claim 8, inside diameter less than 2 mm as in claims 9 and 42 of 0.15 to 0.8 mm (col 4 lines 35-40).

4. Claims 17, 18 and 44 are rejected under 35 U.S.C. 103(a) as being unpatentable over Zha (481) in view of Young et al (US 5,282,964) as in claim 12 above and further in view of Smoot et al (US 4,689,255).

Zha (481) in view of Young (964) does not teach segmentation elements fitted to the outer surface of a housing as in claim 17. Smoot teaches arranging hollow fiber bundles on a pervious sheet (1-fig 2) and then wrapping on the outside surface of a perforated housing (tube) (12 fig 3) (see col 3 line 47 – col 4 line 30). It would be obvious to one of ordinary skill in the art at the time of invention to use the teaching of Smoot in the teaching of Zha in view of Young to have the segmentation elements attached to the outside surface of an inner housing for further protecting the fibers from the force of the fluid flow in the construction of fig 5A and 5B of Zha (481). Regarding claim 18, which depend from claim 17, the teaching of Zha in view of Young has the second cage like structure (fig 5A, 5B and 9 of Zha). Regarding claim 44, the hollow fibers are arranged inside at least one compartment (Zha, fig 3).

5. Claim 47 is rejected under 35 U.S.C. 103(a) as being unpatentable over Zha (481) in view of Rekens (US 6,251,275 B1).

Zha teaches all the elements of claim 47 as in claim 1 above except having hollow fibers of different diameters. Rekens teaches using fibers of different diameters (61,62 and 63 of fig 6, col 6 lines 35-54). It would be obvious to one of ordinary skill in the art at the time of invention to have fibers of different diameters as taught by Rekens in the teaching of Zha for better pressure control in the module.

Response to Arguments

Applicant's arguments filed 9/18/03 have been fully considered but they are not persuasive.

Re the 102 rejection of claims, applicant argues that the packing density of their invention is less than that of the Zha'481 ref and therefore, by amending claim 1 to read packing density as less than 10%, they have overcome the rejection. The examiner disagrees because of the following:
Definitions of packing density:

Zha'481 Ref (col 2 lines 18-21): The packing density of the fibre membranes in a membrane module as used herein is defined as the cross-sectional potted area taken up by the fibre membranes divided by the total potted area and is normally expressed as a percentage.

Application: The term "packing density" refers in percentage terms to the ratio of the volume of all the hollow fiber membranes including their wall volume to the volume of the housing in which the hollow fibers are arranged (para 0007)

Now, $\text{Volume} = \text{cross-sectional area} * \text{length}$

$\text{Packing density (ref)} = \text{cross sectional potted area of fibers} / \text{total cross-sectional potted area}$

$\text{Packing density (app)} = \text{external volume of the hollow fibers} / \text{internal volume of the housing}$
 $= \text{cross-sectional area} * \text{number of fibers} * \text{fiber length} / (\text{cross sectional area of housing} * \text{length}).$

Since the figures 1 and 4 show the fibers as having about same length as the housing, the length factor would cancel out of the equation, leaving behind the definition of packing density as that of the ref. The examiner is unable to ascertain how the packing density of 5% in Zha ref would

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be equivalent to a packing density of 11% by the applicant's definition. Since the applicants have not provided the method as to how they arrived at this conclusion, the examiner sustains the rejection.

Re the 103 rejections, the argument that Zha teaches away: a reference is no less anticipatory if, after disclosing the invention, the reference then disparages it. The question whether a reference "teaches away" from the invention is inapplicable to an anticipation analysis. *Celeritas Technologies Ltd v Rockwell International Corp.*, 150 F.3d 1354, 1361, 47 USPQ2d 1516, 1522-23 (Fed. Cir. 1998).

While Zha teaches increasing packing density, the applicants seem to teach decreasing packing density as being beneficial. However, the range of packing densities in both cases overlap sufficiently for an anticipatory rejection. Rest of the arguments have the basis that the secondary references used do not overcome the deficiencies of Zha ref, ie, the packing density being not less than 10%. However, it may please be noted that the secondary references were not intended for overcoming the deficiencies of Zha ref in terms of packing density, and the applicant has not really overcome the anticipatory rejection of the element of the claims, 'packing density'.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be

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calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Krishnan S Menon whose telephone number is 703-305-5999. The examiner can normally be reached on 8:00-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Wanda L Walker can be reached on 703-308-0457. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0661.

Krishnan Menon
Patent Examiner

Joseph D. Dodge
JOSEPH DODGE
PRIMARY EXAMINER